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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,643	10/31/2000	Masayuki Yokoi	M&M-031-USA	7093

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EXAMINER

GRUN, JAMES LESLIE

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 07/09/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/673,643

Applicant(s)

YOKOI et al.

Examiner

James L. Grun, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 9-12, and 14-16 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 9-12, and 14-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

The amendment filed 28 May 2002 is acknowledged and has been entered. Claims 6 and 13 have been cancelled by the instant amendment. Claims 1-3, 5, 9-12, and 14-16 remain in the case.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant is now required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Submission of corrected drawings may no longer be held in abeyance pending the indication of allowable subject matter. Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.

Claims 1, 5, and 9-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention as is now claimed. Applicant's specification

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provides support for interaction of free enzyme inhibitor with particle immobilized enzyme being increasingly hindered with increasing agglutination of the particles. It is believed that applicant intended --hindered-- at line 14 in claim 1, not the undisclosed direct opposite “unhindered” as is now recited.

Claims 1-3, 5, 9-12, and 14-16 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 2, 5, and 9-11, it is believed that powder --particle-- was intended, as initially recited in the preliminary amendment.

In claim 2, “that” insoluble carrier is not clear and should be --said-- or --the-- insoluble carrier for proper support. The recitations of “in (a) above” and “in (b) and (c) above” are not clear and would appear superfluous in view of the proper antecedent support for “said” elements.

In claim 11, the interrelationships of the components are not clear because it is not clear in what sequence or manner the elements of the reagent are mixed with the sample.

In claims 3, 12, and 14-16, the interrelationships of the components are not clear because it is not clear in what manner enzyme-inhibitor reaction is dependent upon amount, or how the intended use of adding substrate effects an optically detectable change in absorbance [sic.], or how change in absorbance is based on amount. In these claims, “the reaction,” “the amount,” “the presence,” “the...carriers,” and “the addition” lack antecedent basis. In these claims, --

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steric-- is misspelled. The examiner would suggest in claim 3: --(b) an enzyme which reacts with and whose enzymatic activity is inhibited by said enzyme inhibitor, said enzyme being in a free state uncoupled to an antigen or antibody and being increasingly sterically hindered from reacting with said enzyme inhibitor when said insoluble carrier is increasingly aggregated; and (c) a substrate for the enzyme capable of producing an optically detectable indication of reaction with the enzyme; said components (a)-(c) being maintained...--.

In claim 16, previously recited components should be later recited as “the” or “said” component to clarify interrelationships. It is not clear that the components are sequentially mixed with the sample. The examiner would suggest: --sequentially mixing said components (a)-(c) of the immunoassay reagent of claim 3 with a sample suspected of containing a quantity of said target antigen or antibody, wherein a plurality of said insoluble carrier carrying said antibody or antigen reactive with said target antigen or antibody, respectively, are first mixed with the sample under conditions sufficient for a level of agglutination of the carriers when said target antigen or antibody is present in the sample, thereafter adding said component (b) to the mixed sample under conditions sufficient for the enzyme to react with said carrier-coupled enzyme inhibitor to a level dependent upon steric hindrance dependent upon the level of agglutination of the carriers, thereafter adding the enzyme substrate to react with the enzyme which has not reacted with the enzyme inhibitor to produce a level of optically detectable signal, and optically determining the level of signal as an indication of the level of agglutination of the carriers indicative of the quantity of the target antigen or antibody in the sample.--

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Applicant's arguments filed 28 May 2002 have been fully considered but they are not deemed to be persuasive in view of the grounds of rejection set forth in this Office action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (703) 308-3980. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (703) 305-3399.

The phone numbers for official facsimile transmitted communications to TC 1600, Group 1640, are (703) 872-9306, or (703) 305-3014, or (703) 308-4242. Official After Final communications, only, can be facsimile transmitted to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. The above inquiries, or requests to supply missing elements from Office communications, can also be directed to the TC 1600 Customer Service Office at phone numbers (703) 308-0197 or (703) 308-0198.


James L. Grun, Ph.D.
July 8, 2003


CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1640/641